HFI-35 12/12, AE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

d/1626b

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-10

December 11, 1996

Robert D. Malouf
Executive Vice-President
Cheminova America Corporation
6073 N.W. 167th Street, Unit C-20
Miami, Florida 33015

Dear Mr. Malouf:

This letter is written in reference to the marketing of Epigen Feminine Deodorant Spray (Epigen) by your firm. Product labeling, namely your Epigen product flyer distributed with your product, states or suggests that Epigen is useful in treating or preventing genital infections, infectious viruses, genital herpes infections, and sexually transmitted diseases. These claims cause this product to be a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

We are unaware of any evidence which establishes that this drug is generally recognized safe and effective for the intended uses. Therefore, Epigen is a new drug within the meaning of Section 201(p) of the Act, which may not be marketed in this country, since no new drug application has been approved for such drug pursuant to Section 505(b) of the Act.

The drug is misbranded within the meaning of Section 502(a) of the Act in that its labeling is false and misleading because it represents and suggests that there is substantial scientific evidence to establish that the drug is safe and effective for its intended uses, when in fact this is not the case. The drug is further misbranded within the meaning of Section 502(f)(1) of the Act, because its labeling fails to bear adequate directions for the use.

This letter does not represent a comprehensive review of all the products distributed by your firm. As the executive vice-president of your firm, it is your responsibility to assure that all products distributed meet the requirements of the Act and the regulations promulgated thereunder.

We request that you notify this office in writing, within 15 working days of receipt of this letter, stating the action you will take to discontinue the marketing of this drug or otherwise bring it into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products (Section 304) and for injunction (Section 302) against the manufacturer and/or distributor of illegal products.

Your reply should be directed Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District

cc: [redacted]